



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
-----------------	-------------	----------------------	---------------------	------------------

10/727,261

12/02/2003

Hua Wang

22727/04148

5627

24024 7590 03/12/2007
CALFEE HALTER & GRISWOLD, LLP
800 SUPERIOR AVENUE
SUITE 1400
CLEVELAND, OH 44114

EXAMINER

CHO, DAN SUNG C

ART UNIT

PAPER NUMBER

1634

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
--	-----------	---------------

31 DAYS

03/12/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/727,261	WANG ET AL.	
	Examiner	Art Unit	
	Dan-Sung C. Cho	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 December 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-30 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-30 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|--|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input checked="" type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. <u>20070302</u> . |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____. | 6) <input type="checkbox"/> Other: _____. |

DETAILED ACTION

During a telephone interview on 2/27/2007 with Diane Dobrea, the examiner discussed the response dated 12/11/2006 to the previous Requirement for Restriction (mailed 10/11/2006) which included a restriction to a gene fragment and a further restriction on probes and primers to a single gene or gene region and a set of primers and a probe to the elected gene or gene fragment (claims 2-4, 10-12, 14-16 and 24-25; see page 4 and 5) did not include proper election of a single gene fragment to a single nucleic acid sequence. Because applicant argued that the restriction was not clear, a new requirement for restriction is made as set forth below and the restriction requirement mailed on 10/11/2006 has been withdrawn.

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 1-4, 21-24, drawn to a method of detecting Alicyclobacillus and Geobacillus through 16S fragment 1327-1460 detection, classified in class 435, subclass 6.
 - II. Claims 9-12, drawn to a method of detecting Alicyclobacillus and Geobacillus through 16S fragment 752-813 detection, classified in class 435, subclass 6.
 - III. Claims 5-8, drawn to a method of drawn to a method of detecting Alicyclobacillus and Geobacillus through Shc fragment 334-485 detection, classified in class 435, subclass 6.

Art Unit: 1634

- IV. Claims 13-16, 25, drawn to a method of detecting mold and yeast through SEQ ID NO:123, 81-225 fragment detection, classified in class 435, subclass 6.
- V. Claims 17-20, drawn to a method of detecting mold and yeast through SEQ ID NO: 123, 114-238 fragment detection, classified in class 435, subclass 6
- VI. Claim 26, drawn to a kit for detecting Alicyclobacillus and Geobacillus by detecting 16S, 1327-1460 fragment detection, classified in class 435, subclass 24.32
- VII. Claim 27, drawn to a kit for detecting Alicyclobacillus and Geobacillus by detecting 334-485 Sch fragment detection, classified in class 435, subclass 24.32.
- VIII. Claims 28 , drawn to a kit for detecting Alicyclobacillus and Geobacillus by detecting 16S, 752-813 fragment detection, classified in class 435, subclass 24.32
- IX. Claim 29, drawn to a kit for detecting yeast or mold through SEQ ID NO: 123, 81-225 fragment detection, classified in class 435, subclass 24.32
- X. Claim 30, drawn to a kit for detecting yeast or mold through SEQ IN NO: 123, 114-238 fragment detection, classified in class 435, subclass 24.32

Art Unit: 1634

The inventions are distinct, each from the other because of the following reasons: Groups of I-V are distinct and unrelated from each other because I is drawn to a method of detecting Alicyclobacillus and Geobacillus through 16S fragment 1327-1460 detection; II, a method of detecting Alicyclobacillus and Geobacillus through 16S fragment 752-813 detection; III, Alicyclobacillus and Geobacillus through Shc fragment 334-485 detection; IV, a method of detecting mold and yeast through SEQ ID NO:123, 81-225 fragment detection; and V, a method of detecting mold and yeast through SEQ ID NO: 123, 114-238 fragment detection.

Each group is drawn to inventions of detecting different microbes or genes and encompasses distinct inventions. A search of Alicyclobacillus and Geobacillus through 16S fragment 1327-1460, for example, will not be coextensive with the search for Alicyclobacillus and Geobacillus Shc or mold/yeast 16S or other regions of Alicyclobacillus and Geobacillus 16S.

Groups VI to X are distinct and unrelated from each other because VI is drawn to different kits of detecting Alicyclobacillus and Geobacillus or mold and yeast through different gene or gene fragment. Each group is drawn to inventions of kit capable of detecting different DNA fragment. A search of Alicyclobacillus and Geobacillus through 16S fragment 1327-1460, for example, will not be coextensive with the search for Alicyclobacillus and Geobacillus Shc or mold/yeast 16S or other regions of Alicyclobacillus and Geobacillus 16S.

Groups I and V; II and VIII; III and VII; IV and IX; V and X are related as product and process of use. Groups I-V are drawn to methods of microbial detection through the

Art Unit: 1634

detection of 16S or Shc gene or gene fragment, Groups VI-X to kits that can be used to detect specific gene or gene fragment. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the nucleic acids may be used in materially different methods including purification, isolation, hybridization, aptamer, antisense methods, for example.

Groups I and VII-X; II and VI, VII, IX, X; III and VI, VIII, IX, X; IV and VI-VIII, X; V and VI-IX are distinct and unrelated from each other because each combination is not disclosed as capable of being used together. For example, I is drawn to detection methods of Alicyclobacillus and Geobacillus through 16S 1327-1460, while VII is drawn to a kit of detecting Alicyclobacillus and Geobacillus through Sch fragment detection and VIII, to Alicyclobacillus and Geobacillus through 16S 752-813 fragment detection; IX and X, yeast and mold detection.

Further Restriction Requirement

2. Claims 2-4, 6-8, 10-12, 14-16, and 24-25 contain sequences that are patentably distinct from each other because they are distinct and unrelated sequences, i.e. these sequences are unrelated because they have distinct nucleotide sequences.
3. This application contains claims directed to the following patentably distinct species: primers and probes in claims 2-4, 6-8, 10-12, 14-16, and 24-25. The species

Art Unit: 1634

are independent or distinct because they are distinct and unrelated sequences. Primers distinct because they have distinct nucleotide sequences that differ in structures and sequences. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 2-4, 6-8, 10-12, 14-16, and 24-25 are generic. A further sequence restriction is applied to each of Groups I to V. For an elected Group drawn to nucleotide sequences, the Applicant is required to elect one forward primer, one reverse primer and one probe (See MPEP 803.04). For example, if applicant elects Group I, applicant is further required to pick a forward primer in claim 2, a reverse primer in claim 3 and a probe in claim 4. For claim 24, applicant is required to elect the primers and probe elected in claims 2-4. Similarly, for other groups, applicant is required to elect the primers and probe selected in claims 13-16 as applicable.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after

Art Unit: 1634

the election, applicant must indicate which are readable upon the elected species.

MPEP § 809.02(a).

Should applicant traverse on the ground that the nucleic acids are not patentably distinct, applicant should submit evident or identify such evidence now of record showing the species to be obvious variant or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other inventions.

Notice of Possible Rejoinder

4. The examiner has required restriction between product and process claims, namely Groups I/II and VI; III and VII; and IV and V. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. Process claims that depend from or otherwise include all the limitations of the patentable product will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process

Art Unit: 1634

claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai*, *In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Conclusion

5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dan-Sung C. Cho whose telephone number is 571-272-9933. The examiner can normally be reached on Mon - Fri, 8-4 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached on 571-272-0735. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published

Art Unit: 1634

applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Dan-Sung C. Cho
Examiner
AU1634

A handwritten signature in black ink, appearing to read 'R. Shukla', with a horizontal line underneath.

**RAM R. SHUKLA, PH.D.
SUPERVISORY PATENT EXAMINER**